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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,355	12/29/2000	William F. Polley	56301P551	9724
8791	7590	02/20/2004	EXAMINER	
BLAKELY SOKOLOFF TAYLOR & ZAFMAN 12400 WILSHIRE BOULEVARD, SEVENTH FLOOR LOS ANGELES, CA 90025				FLYNN, AMANDA R
		ART UNIT		PAPER NUMBER
		3743		

DATE MAILED: 02/20/2004

(9)

Please find below and/or attached an Office communication concerning this application or proceeding.

6

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/753,355	POLLEY ET AL
	<b>Examiner</b>	<b>Art Unit</b>
	Amanda R. Flynn	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 January 2004.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 16-25 and 27-30 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 21-25 and 27-30 is/are allowed.  
 6) Claim(s) 16-20 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 15 January 2002 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 16 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,489,273 to Whitney et al.

Whitney et al. disclose an introducer (10) for an intravascular device comprising two finger tab portions (18, 20), a tube portion (12) and a hinge portion (the substantially vertical extensions of 18, 20 in Figure 3) between the finger tab portion and the tube portion. During use of the introducer, the user exerts pressure in the direction of Z and Z' (Figure 3) to close the finger tab portions about the hinge portion, and to split the tube along a scoreline (40, 42).

Inasmuch as the term “seamless” has been defined, the finger tab portions, the tube portion and the hinge portion form a seamless introducer. Further, Whitney et al. state that the tube portion and finger tab/hinge portions are integrally formed into one piece through molding (see column 5, lines 13-20). As seen in the figures, the tube is substantially hollow and the finger tab portions are substantially rectangular.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitney et al. in view of U.S. Patent Number 5,263,938 to Orr et al.

Whitney et al. disclose the previously described introducer, but do not specify that the introducer can be made of polycarbonate.

Orr et al. disclose an introducer assembly that is made of polycarbonate, for its "semi-rigid" properties (col. 3, lines 34-37).

It would have been obvious to one skilled in the art at the time the invention was made to have provided the introducer as disclosed by Whitney et al., with a polycarbonate material as taught by Orr et al., to improve the semi-rigid properties of the device.

***Allowable Subject Matter***

5. Claims 21-25 and 27-30 are allowed.
6. The following is an examiner's statement of reasons for allowance: The relevant prior art does not disclose an introducer having a valve that is formed as a single integral piece with the tube of the introducer.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Response to Arguments***

7. Applicant's arguments filed on 5 January 2004 have been fully considered but they are not persuasive.

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On pages 5 and 6 Applicant argues that the Whitney reference does not disclose a hinge that is “a jointed or flexible device on which a door, lid or other swinging part turns.” Applicant also argues that the finger tab portions are attached directly to the sheath without the presence of a hinge.

The Examiner disagrees with these arguments. As seen in Figure 3, Whitney discloses two finger tab portions that are connected to the tube by “substantially vertical extensions.” In contrast with Applicant’s argument, the actual rectangular finger tab portions are not directly connected to the tube, but are connected by the “substantially vertical extensions.” When pressure is applied to the finger tabs in the directions noted, the finger tabs pivot via the connection of the “substantially vertical extensions” to split the sheath. This action clearly meets applicant’s proposed definition of a hinge. The finger tabs are a “swinging part” which turns about the hinge. The connection between the “substantially vertical extensions” and the tube provides an obvious pivot point, or hinge, to allow the sheath to be split. The Examiner maintains the instantly applied rejections.

8. Applicant’s arguments, with respect to claims 21-25 and 27-30, have been fully considered and are persuasive. The rejection of these claims has been withdrawn.

### *Conclusion*

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

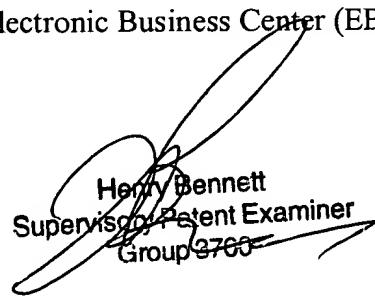
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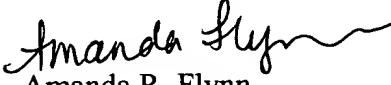
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda R. Flynn whose telephone number is 703-306-4056. The examiner can normally be reached on Monday-Thursday, 8:30 - 6:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Henry Bennett  
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Amanda R. Flynn  
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Art Unit 3743

  
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